PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	DePhillipo and Ricciardi
Serial No.	09/826,522
Filed	April 5, 2001
Art Unit	1634
Confirmation No.	2835
Examiner	Myers
Title	Kits and Methods for Assessing Oxidative Stress
Atty. Docket No.:	GNLK 03

Cincinnati OH 45202 April 30, 2007

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF ROBERT P. RICCIARDI, Ph.D.
PURSUANT TO 37 CFR §1.132

I, ROBERT P. RICCIARDI, declare as follows:

1. I am an inventor of the referenced application. I was awarded a Ph.D. in Cellular and Molecular Biology from the University of Illinois in 1977. I have over 26 years of experience in this field, which is the subject matter of my invention.

2. I have read the outstanding Office Action, and understand the Examiner's position.

3. I respectfully disagree that claim 105 is not enabled and is indefinite, for at least the following reasons.

4. It is my opinion that one skilled in the art would know how to obtain, without undue experimentation, a sequence for a human gene encoding a superoxide dismutase and for a human gene encoding a catalase. For example, one would interrogate the human genome sequence by searching available database sites; a popular site that would provide this information is the National Center for Biotechnology Information (NCBI) database, available at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=Nucleotide.

5. On the "Search" dropdown menu on the upper left, select "gene" and type in "human superoxide dismutase" in the "for" box and perform the search. A variety of genes will appear, such as SOD1 (superoxide dismutase 1). Look through the list and find the desired gene, in this example, "#1 (human)". On the "Search" dropdown menu on the upper left, select "gene" and type in "human catalase" in the "for" box and perform the search. The catalase (CAT) gene in this example is #2. Access the desired gene (click on it) and all the related information, including sequence, for the gene appears.

6. Another site that would provide information on polymorphisms (single nucleotide polymorphisms (SNP)) is http://www.ncbi.nlm.nih.gov/SNP.

7. It is my opinion that one skilled in the art would know how to determine if a polymorphism in a human gene encoding a superoxide dismutase and a human gene encoding a catalase has been identified as associated with a pathology. Polymorphisms showing associations with a pathology are reported in the literature, which can be queried by searching publication databases such as PubMed, available at file:///Users/robertiricciardi/Desktop/PubMed.html.

8. As one example, Kirmura et al. reported that a polymorphism in the manganese-containing superoxide dismutase gene (referred to as either MnSOD or SOD2) is manifested at codon position 16 in the protein as a nucleotide T to C alteration, resulting in the corresponding alteration of the codon from valine to alanine, is associated with exudative age-related macular degeneration (Am J Ophthalmol. (2000) 130:769). As another example, Alexander et al. reported a sporadic case of amyotrophic lateral sclerosis (ALS) in which heterozygosity for an A-to-G transition at nucleotide 112 of exon 4 of SOD1 was discovered (Ann. Neurol. (2002) 52: 680). As another example, Jiang et al. reported an association between essential hypertension, defined as elevation of systolic blood pressure, and a single-nucleotide polymorphism (SNP) located 844 bp upstream of the start codon of the CAT gene (Hum. Genet. (2001) 109: 95).

9. Alternatively, one skilled in the art may access the polymorphism by continuing from the search I describe in ¶5. Viewing the SOD1 gene page, scroll down to "phenotypes", providing gene-related pathologies such as ALS. Click on the desired pathology to view summaries and references for the association of the gene with the pathology. For example, 15 to 20% of cases of familial ALS, referred to as ALS1, are associated with mutations in the superoxide dismutase-1 gene on chromosome 21q22.1. Click on the number hyperlink after SOD1 to access a page further describing the involved molecular genetics. Polymorphisms can also be found under the "SNP" selection on the right side of the SOD1 gene web page.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the subject application or any patent issued thereon.

April 30, 2004
Date

Robert P. Ricciardi, Ph.D.